



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

10/759,985

Confirmation No.: To be assigned

Applicant:

Schinazi *et al.*January 16, 2004

Filed: TC/A.AU.:

To be assigned
To be assigned

Examiner:

Docket No.:

18085.105327 EMU 133 CON 5

Customer No.:

20786

Title:

(5-Carboxamido or 5-Fluoro)-(2',3'-Unsaturated or 3'-Modified)-Pyrimidine

Nucleosides

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Transmittal of Information Disclosure Statement

Sir:

The citation of information on the attached Form PTO-1449 is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. A copy of each of references BW, DJ, HF and JK is enclosed; copies of the remaining references were cited in the following parent applications: U.S.S.N. 10/146,779, which issued as 6,680,303 on January 20, 2004; 09/677,161, which issued as 6,391,859 on May 21, 2002; 09/310,323, which issued as 6,232,300 on May 15, 2001; 09/001,084, which issued as 5,905,070 on May 18, 1999; and 08/379,276, which issued as 5,703,058 on December 30, 1997. The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

Because this Information Disclosure Statement is being submitted within three months of the filing date, the Applicants do not believe that any additional fees are due; however, the Commissioner is hereby authorized to charge any fees due or credit any overpayment to Deposit Account No. 11-0980.

Respectfully submitted,

Madeline I. Johnston

Reg. No. 36,174

Date: April 30, 2004 King & Spalding, LLP

191 Peachtree Street, N.E., Atlanta, GA 30303 Office: (404)572-4600/ Fax: 404-572-5145

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 30, 2004.

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TRADEN TO Substitute for for	orm 1449A/PTO			Complete if Known			
·				Application Number	10/759,985		
_	MATION DISC			Filing Date	January 16, 2004		
STATEMENT BY APPLICANT				First Named Inventor	Schinazi et al.		
			1	Group Art Unit	Unassigned		
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Sheet	1	of	14	Attorney Docket Number	18085.105327 EMU 133 CON 5		

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*		-	•	U.S. PATENT DOCUMENTS		
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	5 A 440 MMO			Complete if Known			
Submitted to	Submitted for form 1449/PTO			Application Number	10/759,985		
	INFORMATION	DISCLOS	HRE	Filing Date	January 16, 2004		
	STATEMENT BY			First Named Inventor	Schinazi et al.		
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				Examiner Name	Unassigned		
Sheet	2	of	14	Attorney Docket Number	18085.105237 EMU 133 CON 5		

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Submitted for	form 1449/PTO			Application Number	10/759,985			
	INFORMATION D	OISCLOS	SURE	Filing Date January 16, 2004				
	STATEMENT BY			First Named Inventor	Schinazi et al.			
				Group Art Unit	Unassigned			
				Examiner Name	Unassigned			
Sheet	3	of	14	Attorney Docket Number	18085.105237 EMU 133 CON 5			

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Examiner	Cite	For	eign Patent Docum	ent	Name of Patentee or Applicant	Date of Publication of	Pages, Columns, Lines,	Τ
Initials *	No. 1	Office 3	Number Kind ((if know		of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	
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Sheet	4	of	14	Attorney Docket Number	18085.105237 EMU 133 CON 5		

·				FORE	IGN PATENT DOCUMENTS			
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Examiner	Date	
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
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3447379 2.DOC OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, Cite Examiner symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. Initials * No. KA PAI et al., "Inhibition of Hepatitis B Virus by a Novel L-Nucleoside, 2'-Fluoro-5-Methyl-.beta.-L-Arabinofuranosyl Uracil," Antimicrob. Agents and Chemother., 40(2):380-386 (February 1996). KB PAINTER et al., Chem. Abst. 117(23):226298z (December 7, 1992). PAINTER et al., Chem. Abst. 118(6):45750r (1992). KC PARKER et al., "Mechanism of Inhibition of Human Immunodeficiency Virus Type 1 Reverse KD Transcriptase and Human DNA Polymerase .alpha., .beta.0 and .gamma. by the 5'-Triphosphates of Carbovir, 3'-Azdo-3'-deoxythymidine, 2',3'-Dideoxyguanosine, and 3'-Deoxythymidine," J. Biological Chem., 208(3), 1754-1762 (January 25, 1991). PHILPOTT et al., "Evaluation of 9-(2-phophonylmethoxyethyl) adenine therapy for feline KE immunodeficiency virus using a quantitative polymerase chain reaction," Vet. Immunol. and Immunopathol., 35:155-166 (1992). KF PIRKLE and POCHANSKY, "Chiral Stationary Phases for the Direct LC Separation of Enantiomers," Advances in Chromatography, Giddings, J.C., Grushka, E., Brown, P.R., eds.: Marcel Dekker: New York, 1987; vol. 27, Chap. 3, pp. 73-127. KG RICHMAN, D. D., "The Toxicity of Azidothymidine (AZT) in the Treatment of Patients with AIDS and AIDS-Related Complex," N. Eng. J. Med., 317(4):192-197 (July 23, 1987). KH ROBINS et al., "Purine Nucleosides. XXIX. The Synthesis of 2'-Deoxy-L-adenosine and 2'-Deoxy-Lguanosine and Their Alpha Anomers," J. Org. Chem., 87:636-639 (March 1970). Van ROEY et al., "Absolute Configuration of the Antiviral Agent (-)-cis-5-Fluoro-1-[2-ΚI (Hydroxymethyl)-1,3-Oxathiolan-5-yl] Cytosine," Antiviral Agents and Chemotherapy, 4(6), 369-375 (1993).SATSUMABAYASHI, S. et al., "The Synthesis of 1,3-Oxathiolane-5-one Derivatives," Bull. Chem. KJ Soc. Japan, 45:913-915 (March 1972). SCHINAZI, R.F., et al., "Antiviral Drug Resistance Mutations in Human Immunodeficiency Virus Type KK 1 Reverse Transcriptase Occur in Specific RNA Structural Regions," Antimicrobial Agents and Chemotherapy, 38(2):268-274 (February 1994). SCHINAZI, R.F., et al., "Characterization of Human Immunodeficiency Viruses Resistant to KL Oxathiolane-Cytosine Nucleosides," Antimicrobial Agents and Chemotherapy, 37(4):875-881 (April KM SCHINAZI, R.F., et al., "Pure Nucleoside Enantiomers of beta-2',3'-Dideoxycytidine Analogs Are Selective Inhibitors of Hepatitis B Virus In Vitro," Antimicrobial Agents and Chemotherapy, 38(9):2172-2174 (Septmeber 1994).

Examiner		Date	
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¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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0.1	C 1.440/PTO			Complete if Known		
Submitted for form 1449/PTO				Application Number	10/759,985	
I	NFORMATION I	DISCLOS	URE	Filing Date	January 16, 2004	
	STATEMENT BY			First Named Inventor	Schinazi et al.	
				Group Art Unit	Unassigned	
				Examiner Name	Unassigned	
Sheet	12	of	14	Attorney Docket Number	18085.105237 EMU 133 CON 5	

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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	6
	LÅ	SCHINAZI, R.F., et al., "Activities of the Four Optical Isomers of 2',3'-Dideoxy-3'-Thiacytidine (BCH-189) against Human Immunodeficiency Virus Type 1 in Human Lymphocytes," Antimicrobial Agents and Chemotherapy, 36(3):672-676 (March 1992).	
	LB	SCHINAZI, R.F., et al., "Insights into HIV Chemotherapy," AIDS Research and Human Retroviruses 8(6):963-990 (1992).	
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	LE	SCHINAZI, R.F., et al., "Substrate Specificity of Escherichia Coli Thymidine Phosphorylase for Pyrimidine Nucleoside with an Anti-Human Immunodefiency Virus Activity," <i>Biochemical Pharmacology</i> , 44(2):199-204 (1992).	
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C 1 1 C	. C. 1440 mTO			Complete if Known		
Submitted io	or form 1449/PTO			Application Number	10/759,985	
	INFORMATION	DISCLOSE	IRE	Filing Date	January 16, 2004	
	STATEMENT BY			First Named Inventor	Schinazi et al.	
				Group Art Unit	Unassigned	
				Examiner Name	Unassigned	
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	MA	STORER, R., et al., "The Resolution and Absolute Stereochemistry of the Enantiomeris of cis-1-[2-(Hydromethyl)]-1,3-Oxathiolan-5-yl)cytosine (BCH189): Equipotent Anti-HIV Agents," <i>Nucleosides & Nucleotides</i> , 12(2):225-236 (1993).	
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:	ME	TISDALE et al., "Rapid In Vitro Selection of Human Immunodeficiency Virus Type 1 Resistant to 3'-Thiacytidine Inhibitors Due to a Mutation in the YMDD Region of Reverse Transcriptase," <i>Proc. Nat. Acad. Sci. USA</i> , 90:5653-5656 (June 1993).	
	MF	TSURIMOTO, Toshiki, et al., "Stable Expression and Replication of Hepatitis B Virus Genome in an Integrated State in a Human Hepatoma Cell Line Transfected with the Cloned Viral DNA," Proc. Natl. Acad. Sci. USA, 84:444-448 (January 1987).	
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	MI	VOLK, Wesley, A., editor, "Hepatitis," <u>Essentials of Medical Microbiology</u> , J.B. Lippincott Company, (Philadelphia/Toronto), 2nd Ed., pp. 609-618 (1982).	
	MJ	VORBRUGGEN et al., "Nucleoside Synthesis with Trimethylsilyl Triflate and Perchlorate as Catalysts," Chem. Ber., 114:1234-1255 (1981).	
	MK	WILSON et al., "The 5'-Triphosphates of the (1) and (+) Enantiomers of cis-5-Fluoro-1-[2-(Hydroxymethyl)-1,3-Oxathiolane-5-yl]Cytosine Equally Inhibit Human Immunodeficiency Virus Type I Reverse Transcriptase," Antimicrob. Agents and Chemother., 37(8):1720-1722 (August 1993).	
	ML	WILSON, L.J., et al., "A General Method for Controlling Glycosylation Stereochemistry in the Synthesis of 2!-Deoxyribose Nucleosides," <i>Tetrahedron Lett.</i> , 31(13):1815-1818 (1990).	
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-	NA	YOKOTA et al., "Comparative Activities of Several Nucleoside Analogs Against Duck Hepatitis B Virus In Vitro," Antimicrobial Agents and Chemotherapy, 34(7):1326-1330 (July 1990).			
	NB	ZHU, Zhou, et al., "Cellular Metabolism of 3'-Azido-2',3'-Dideoxyuridine with Formation of 5'-O-Diphophoshexase Derivatives by Previously Unrecognized Metabolic Pathways of 2'-Deoxyuridine Analogs," <i>Molecular Pharmacology</i> , 38::929-938 (1990).			

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